

**REMARKS/ARGUMENTS**

This document responds to the Final Office Action mailed on October 1, 2008. In that Office Action, claims 1-18 were examined, and all claims were rejected. More specifically, claims 1 and 10 were rejected as allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Claims 1-4, 6, 7, 9-13, 15-16, and 18 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Wheeldon et al. (USPN 4,670,007) in view of Hadzic et al. (USPN 5,910,135). Claims 5, 8, 14, and 17 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Wheeldon in view of Hadzic, and further in view of general knowledge in the art. Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

Claims 1 and 10 are being amended. No new claims are being added, and no claims are being cancelled.

**Examiner's Interview**

The undersigned thanks Examiner Bouchelle for the telephone interview conducted on February 23, 2009. A summary of the interview is being filed herewith as a separate document.

**Claim Rejections – 35 U.S.C. § 112, First Paragraph**

Claims 1 and 10 were rejected as allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Specifically, the rejection alleges that the feature of “the processor not being deployed to adjust the rate of delivery of the fluid,” recited in claim 1 and the feature of “the signal not being used to adjust the rate of flow of the sterile fluid,” recited in claim 10 are not supported in the specification. During the telephone interview, Examiner Bouchelle indicated that the claims were adequately supported by at least FIG. 1, which shows that output from the processor is not electronically connected to the pump. Accordingly, Applicant respectfully requests the withdrawal of this rejection.

**Claim Rejections of Claims 1-4, 6, 7, 9-13, 15-16, and 18 -- Under 35 U.S.C. § 103**

Claims 1-4, 6, 7, 9-13, 15-16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon et al. (USPN 4,670,007) hereinafter “Wheeldon” in view of Hadzic et al. (USPN 5,910,135) hereinafter “Hadzic.” Applicant respectfully traverses this rejection, because Wheeldon and Hadzic, alone and in combination, fail to teach all of the elements of the claims.

**Claims 1-9**

As described previously, the claims in the present application are directed to systems and methods of accurately and rapidly delivering sterile fluids for use in a cosmetic surgery procedure, such as lipoplasty or filling of saline breast implants. These claimed systems are significantly different than systems used for intravenous (IV) delivery of fluids to a patient as described in Wheeldon and Hadzic. As described below, Wheeldon and Hadzic, alone and in combination, fail to teach all of the elements of claims 1-9.

The Wheeldon system is distinct from the system claimed in claim 1 and is not capable of being used in procedures contemplated by the present application. Claim 1 is directed to “a system for rapidly delivering and accurately monitoring the delivery of a volume of sterile fluid to a targeted anatomical site or an implantable device in a cosmetic surgery procedure” (emphasis added). Claim 1 specifically recites “a pump for rapidly pumping 100 ml to 5000 ml of the sterile fluid from the container to a targeted anatomical site or implantable device” (emphasis added). As someone of ordinary skill in the art would appreciate, the Wheeldon system is only capable of being used for very slow IV administration of fluids and is not useful in rapid delivery of fluids to a targeted anatomical site. See *Wheeldon*, col. 4, lns. 20-25 (“The present invention is particularly designed for controlling an intravenous infusion system utilising a peristaltic pump and a standard administration set for delivery of fluid to a patient and enables such a system accurately and uniformly to perform infusions in accordance with a selected delivery rate.”). An IV system such as Wheeldon’s is simply not useful in delivering fluids to a targeted anatomical site or for delivery of fluids rapidly enough to, for example, fill saline breast implants or generate sufficient pressure to infuse fatty tissues as is necessary in lipoplasty. Indeed, one might question whether the variable speed pump could be adjusted quickly enough

both electronically and mechanically to deliver a precise volume of fluid at high speeds. Perhaps this is why there is no mention of rapid flow rates in Wheeldon.

As a further point of distinction, claim 1 recites, *inter alia*, “a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time” (emphasis added). In contrast, the Wheeldon system includes a processor and a weight sensing device that are used in calculating the actual flow rate of fluid being delivered intravenously to a patient. If the actual flow rate differs from the desired flow rate, output from the processor will adjust the speed of the pump. As stated in Wheeldon:

the signals supplied by the weight sensing device 2 are processed with respect to time by the CPU 30 to produce data identifying the actual fluid delivery rate and the CPU then compares this actual delivery rate data with the selected rate data and regulates the motor speed [sic], when the actual delivery rate does not correspond with the selected delivery rate, in order to eliminate the error.

*Wheeldon*, col. 8, lns. 18-25. Wheeldon fails to teach a processor “wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time.” As noted in the quoted language above, such a feature is against the teachings of Wheeldon. For this additional reason, claim 1 is distinct from Wheeldon.

Hadzic does not compensate for the deficiencies of Wheeldon. Hadzic teaches a drip IV system. The Hadzic system does not even teach the use of a pump; rather the Hadzic system is a gravity flow system. The system includes a separate microflow path and a macroflow path that can be operated separately or combined to produce a low flow rate or a higher flow rate. Such a gravity flow system however is not the same as “a system for rapidly delivering and accurately monitoring the delivery of a volume of sterile fluid to a targeted anatomical site or an implantable device in a cosmetic surgery procedure,” as claimed in claim 1. The gravity flow IV system of Hadzic could not rapidly deliver sterile fluid to “a targeted anatomical site or implantable device,” as recited in claim 1. As a person ordinary skill in the art would appreciate, a gravity flow system is not useful in the cosmetic surgery procedures described in the present

application. For example, the gravity flow system cannot generate sufficient pressure to infuse fatty tissues as is necessary in lipoplasty.

Furthermore, because the Hadzic system is a gravity flow system it also fails to teach “a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time,” as recited in claim 1. Indeed, as described in the previous response and emphasized below, Hadzic teaches against using a pump. For these reasons, the combination of Wheeldon and Hadzic fail to teach all of the elements of claim 1. Claims 2-9 depend upon claim 1 and are allowable for at least the same reasons.

In addition to Wheeldon and Hadzic’s failure to teach all of the elements of claim 1, they also include teachings against their combination. As indicated in the previous response, Wheeldon teaches away from gravity infusion and drip systems, because of their inability to accurately control the amount and rate of fluid delivery. *See Wheeldon*, col. 3, lns. 33-38. Hadzic considers the ability of a user to observe the rate as critically important. *See Hadzic*, col. 4, lns. 24-53. Accordingly, these teachings would guide a person of ordinary skill in the art away from using a system that does not enable the user to monitor the formation of drips, such as the Wheeldon system. Both of the references have teachings that are inconsistent with their combination.

The U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.* maintains that language that teaches away from combining two elements must be considered in an obviousness analysis. *See KSR*, 82 USPQ 2d at 1395 (citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966)). Since the KSR decision, the U.S. Court of Appeals for the Federal Circuit and the U.S. Board of Patent Appeals and Interferences have consistently held that teachings away must be considered in an obviousness analysis. *See, e.g., In Re Sullivan*, 498 F.3d at 1351 (“[e]vidence rebutting a prima face case of obviousness can include: . . . evidence ‘that the prior art teaches away from the claimed invention in any material respect’”) (citations omitted); *Ex parte Carlucci*, BPAI Appeal No. 2008-1092 at p. 8 (“[f]urther, not only does Brode lack suggestion or motivation for the use of the skin care compositions on sanitary pads, but we agree with Appellants that Brode teaches away from the combination.”) (citations omitted); *Ex parte Hobbs*, BPAI Appeal No. 2007-4198 at p. 6 (“[a]s the Dutta reference applied in the rejection fails to

‘display the advertisement on the customer interface when processing the job ticket’ instead of on the printed documents and teaches away from such a modification, we cannot sustain the rejection.”); and *Ex parte Seto*, BPAI Appeal No. 2007-4271 at p. 8 (“We thus conclude that Urai and Hashimoto teach away from modification of Urai’s system to produce automatic braking when it is determined that collision is avoidable by operation of the steering wheel but unavoidable by operation of the brake pedal. ‘[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.’”) (citing *KSR Int’l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007)). Applicant thus respectfully submits that claims 1-9 are further not obvious over Wheeldon and Hadzic because Wheeldon teaches away from using a drip system as disclosed by Hadzic, and Hadzic teaches away from the use of a mechanically variable flow control, such as a used by Wheeldon.

#### Claims 10-18

Claim 10 is directed to “a method for rapidly delivering and accurately monitoring the delivery of a volume of sterile fluid to a targeted anatomical site or implantable device in a cosmetic surgery procedure.” Claim 10 also recites “processing with a processor the electronic signal from the strain gauge to display the volume of sterile fluid removed from the container from time-to-time, wherein output from the processor is not electronically connected to the pump and wherein the processor does adjust the speed of the pump at any time.”

Wheeldon and Hadzic, alone and in combination, fail to teach a method as claimed in claim 10. As noted above, Wheeldon and Hadzic describe IV fluid delivery systems that are not useful in the cosmetic surgery procedures contemplated by the present application, which require the rapid delivery of fluid to a targeted anatomical site or anatomical device. Moreover, neither reference teaches a method that would include “processing with a processor the electronic signal from the strain gauge to display the volume of sterile fluid removed from the container from time-to-time, wherein output from the processor is not electronically connected to the pump and wherein the processor does adjust the speed of the pump at any time.” The combination of Wheeldon and Hadzic thus fails to teach all of the elements of claim 10. Claims 11-18 depend upon claim 10 and are allowable for at least the same reasons.

**Claim Rejections Of Claims 5, 8, 14, and 17 Under 35 U.S.C. § 103**

Claims 5, 8, 14, and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wheeldon in view of Hadzic, and further in view of general knowledge in the art. Claims 5, 8, 14, and 17 depend upon one of claims 1 and 10 and are patentable for the same reasons as discussed above with respect to claims 1 and 10.

**Conclusion**

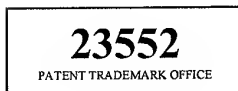
This document responds to the Final Office Action mailed on October 1, 2008. Still, the Final Office Action may contain arguments and rejections that are not directly addressed by this document because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this document to directly address an argument raised in the Final Office Action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the Final Office Action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this document, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability.

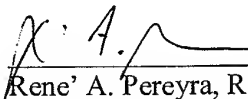
Fees for the RCE and a 3-month extension of time are being paid herewith. No additional fees are believed due. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

In light of the above remarks, it is believed that the application is now in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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